

Classification of Topical Drug Products

A Way Forward to Reduce Regulatory Burden

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Topical Drug Classification System (TCS)

- **TCS** is a framework for classifying topical drug products based on its qualitative and quantitative composition, microstructure arrangements of matter and *in vitro* release (IVR).
- **TCS** when applied will help in approval of generic topical drug products, without conducting *in vivo* studies, but assuring product safety and efficacy.
- Topical drug products are classified into 4 classes.

Topical Drug Classification System, TCS

**Q1, Q2 Same
Q3 Same**

TCS class 1

**Q1, Q2 Same
Q3 Different**

TCS class 2

**Q1, Q2 Different
Q3 Same**

TCS class 3

**Q1, Q2 Different
Q3 Different**

TCS class 4

BCS and TCS

Oral drug products

Topical drug products

BCS

TCS

High Permeability
High Solubility
BCS class 1

High Permeability
Low Solubility
BCS class 2

Q1, Q2 Same
Q3 Same
TCS class 1

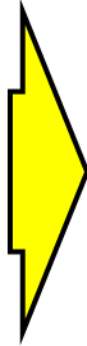
Q1, Q2 Same
Q3 Different
TCS class 2

Low Permeability
High Solubility
BCS class 3

Low Permeability
High Solubility
BCS class 4

Q1, Q2 Different
Q3 Same
TCS class 3

Q1, Q2 Different
Q3 Different
TCS class 4



Biowaiver



BE



Biowaiver



BE

Ref: VP Shah et al., Int J of Pharmaceutics. 509: 35-40, 2016.

Acyclovir Cream

Studies in Progress to validate TCS

- 12 formulations are prepared with changes in manufacturing process or composition to yield drug products in **TCS class 1, 2 or 3**.
- We will be conducting
 - *in vitro* release tests (IVRT), *in vitro* permeation test (IVPT),
 - Assessment of Q3, Microstructure measurements, Rheology.
 - *In vivo* testing – Pilot study using DPK

Moving Forward on TCS

- We would like to invite the Agency to join us on this collaborative effort and to support the present work which may facilitate the evaluation of the potential use of TCS in the development of topical drug products and their regulatory evaluation.

Conclusion

- **A practical and science based classification system, TCS, for topical drug products is proposed.**
- TCS will facilitate:
 - Generic product development, reduce the regulatory burden and assure product quality across all therapeutic classes.
 - Availability of topical drug products to patients and consumers at a more reasonable cost.

***Thank you for
your Attention***