

# 10216 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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| <u>Name</u>                                                  | <u>Additional Requirement</u> | <u>Comment (ECF)</u>                                                                                                                                                                                                                          |
|--------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Phenazopyridine Hydrochloride<br>Tablets, NF, 0.1 Gram, 100s | Additional identity test      | NF monograph specifies two identity tests, both of which are quite specific. Additional identification tests are redundant.                                                                                                                   |
| Undecylenic Acid Ointment,<br>Compound, NF, 28.35 Gram       | Iodine Number                 | NF monograph for the active ingredient does include such a test and specification. NF requires all dosage forms to be prepared with active ingredients complying with their pertinent standards. Hence, this specification is redundant here. |